DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services

Food and Drug Administration
Rockville MD 20857

September 26, 2005

W. David Hager, M.D.
Department of Obstetrics and Gynecology
University of Kentucky
800 Rose Street, Room MN 318
Lexington, KY 40536-0084

Dear Dr. Hager:

This is in response to your letter dated August 22, 2005, to Dr. Lester Crawford, Commissioner, Food and Drug Administration (FDA), regarding your concerns about the switch of Plan B (levonorgestrel) from prescription to over-the-counter (OTC) status. Your letter was forwarded to my office in the Center for Drug Evaluation and Research (CDER) for response.

Thank you for writing us again and expressing your thoughts and concerns regarding this important issue. As you may know, FDA has again created a public docket for the purpose of receiving comments regarding the switching of Plan B to OTC status. This docket will be open for public comment until November 1, 2005. I have taken the liberty of forwarding your letter with enclosure to the Division of Dockets Management so that it can be recorded and considered as an official comment.

If you would like to make additional comments, electronic comments can be submitted to http://www.fda.gov/dockets/ecomments. Select docket "2005N-0345 - Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-The-Counter Drug Product" and follow the prompts to submit your statement. Written comments can be submitted to Dockets Management Branch, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Again thank you for making your thoughts and concerns known to the Agency.

Sincerely,

Donald Dobbs
Division of Drug Information (HFD-240)
Office of Training and Communications
Center for Drug Evaluation and Research
Food and Drug Administration

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